

ENTERED

November 07, 2017

David J. Bradley, Clerk

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

UNITED STATES OF AMERICA

§
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§
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v.

CRIMINAL ACTION H-11-803-1
CIVIL ACTION H-16-0749

LAWRENCE STOWE

§

MEMORANDUM OPINION AND ORDER

Defendant Lawrence Stowe, proceeding *pro se*, filed a motion and supplemental motion to vacate, set aside, or correct his sentence under 28 U.S.C. § 2255 (Docket Entries No. 189, 194). The Government filed a motion to dismiss (Docket Entry No. 200), to which Defendant filed a response (Docket Entry No. 201).

Having reviewed the section 2255 motions, the motion to dismiss, the response, the record, and the applicable law, the Court GRANTS the motion to dismiss and DENIES the section 2255 motion and supplemental motion for the reasons that follow.

Background and Claims

On September 7, 2012, and pursuant to a written plea agreement, Defendant pleaded guilty to conspiracy to violate the Food, Drug and Cosmetic Act [“FDCA”], with the intent to defraud and mislead, by causing the introduction of new drugs into interstate commerce that were misbranded and unapproved, in violation of 18 U.S.C. § 371 (count one); with intent to defraud and mislead, introducing and delivering for introduction into interstate commerce a vaccine commonly referred to as Immune Factor G40 that was misbranded in that the promotional material was false and misleading, in violation of 21 U.S.C. §§ 331(a), 333(a)(2) and 352(a) and 18 U.S.C. § 2 (count 23); and, with intent to

defraud and mislead, introducing and delivering into interstate commerce, a vaccine commonly referred to as Immune Factor G40, which was a new drug within the meaning of the FDCA and not approved for use in the United States, in violation of 21 U.S.C. §§ 331(d) and 333(a)(2) (count 24).

On May 2, 2014, this Court sentenced Defendant to a total of 78 months in prison, 60 months for the conspiracy count and 18 months each for the substantive counts, to run concurrently with each other, but consecutively to the 60 months imposed for the conspiracy count. The Court also imposed a three-year term of supervised release and \$419,358.00 in restitution.

Defendant raises the following grounds for habeas relief in this proceeding:

(1) Ineffective Assistance of Counsel:

- (a) “Petitioner received ineffectiveness of counsel during the plea phase when counsel failed to subject the prosecutions [*sic*] case to meaningful adversarial [*sic*] testing, [and] failure to advise regarding the actual consequences.”
- (b) “Counsel failed to pursue petitioner’s defense and to investigate the FDA reports which the FDA did not follow procedural due process of law.”
- (c) Counsel failed to raise *mens rea* as a defense.
- (d) Counsel failed to challenge calculations and relevant conduct used at sentencing.
- (e) Counsel “failed to raise the claim that his client was not a manufacturer or promoter of the immune-therapy products,” which would have established his actual innocence.

(2) Actual Innocence:

- (a) “Actual innocence is factual innocence and petitioner’s actions do not give rise to criminality.”
- (b) “Petitioner Stowe is actually innocent pursuant to the provisions of the [FDCA] as he is not a manufacturer of drugs and at all times worked through licensed physicians.”

The Government argues that these claims are barred by the valid waiver of collateral review provision in Defendant’s written plea agreement. It also argues that the claims have no merit.

Legal Standards

Generally, there are four grounds upon which a defendant may move to vacate, set aside, or correct his sentence pursuant to section 2255: (1) the imposition of a sentence in violation of the Constitution or the laws of the United States; (2) a lack of jurisdiction of the district court that imposed the sentence; (3) the imposition of a sentence in excess of the maximum authorized by law; and (4) the sentence is otherwise subject to collateral attack. 28 U.S.C. § 2255; *United States v. Placente*, 81 F.3d 555, 558 (5th Cir. 1996). Section 2255 is an extraordinary measure, and cannot be used for errors that are not constitutional or jurisdictional if those errors could have been raised on direct appeal. *United States v. Stumpf*, 900 F.2d 842, 845 (5th Cir. 1990). If the error is not of constitutional or jurisdictional magnitude, the movant must show the error could not have been raised on direct appeal and would, if condoned, result in a complete miscarriage of justice. *United States v. Smith*, 32 F.3d 194, 196 (5th Cir. 1994).

Ineffective Assistance of Trial Counsel

The United States Supreme Court's decision in *Strickland v. Washington* provides the familiar two-pronged test for establishing a claim of ineffective assistance of counsel:

First, the defendant must show that counsel's performance was deficient. This requires showing that counsel made errors so serious that counsel was not functioning as the "counsel" guaranteed the defendant by the Sixth Amendment. Second, the defendant must show that the deficient performance prejudiced the defense. This requires showing that counsel's errors were so serious as to deprive the defendant of a fair trial, a trial whose result is reliable. Unless a defendant makes both showings, it cannot be said that the conviction . . . resulted from a breakdown in the adversary process that renders the result unreliable.

466 U.S. 668, 687 (1984). A court need not address both components of the inquiry if the defendant makes an insufficient showing on one. *Carter v. Johnson*, 131 F.3d 452, 463 (5th Cir. 1997) ("Failure to prove either deficient performance or actual prejudice is fatal to an ineffective assistance claim.").

A counsel's performance is strongly presumed to fall within the wide range of reasonable professional assistance. *Premo v. Moore*, 562 U.S. 115, 121 (2011). To overcome that presumption, a habeas petitioner must "show that counsel made errors so serious that counsel was not functioning as the counsel guaranteed the defendant by the Sixth Amendment." *Id.* at 121–22 (internal quotations omitted). The standard for judging counsel's representation is a deferential one. "The question is whether an attorney's representation amounted to incompetence under 'prevailing professional norms,' not whether it deviated from best practices or most common custom." *Id.*

“A plea of guilty admits all the elements of a formal criminal charge and waives all non-jurisdictional defects in the proceedings leading to conviction.” *United States v. Owens*, 996 F.2d 59, 60 (5th Cir. 1993). A guilty plea also eliminates objections to searches and seizures that violate the Fourth Amendment. *United States v. Cothran*, 302 F.3d 279, 285–86 (5th Cir. 2002). Where, as here, a defendant has pleaded guilty and waived his right to file a motion pursuant to section 2255, the only ineffective assistance of counsel claim to survive the waiver is one claiming the ineffective assistance “directly affected the validity of waiver or the plea itself.” *United States v. White*, 307 F.3d 336, 343 (5th Cir. 2002).

Moreover, a habeas petitioner must show that, “but for counsel’s errors he would not have pleaded guilty and would have insisted on going to trial” and that going to trial “would have given him a reasonable chance of obtaining a more favorable result.” *United States v. Batamula*, 823 F.3d 237, 240 (5th Cir. 2016) (en banc) (internal citation and quotation omitted).

The pleadings of a *pro se* prisoner litigant are reviewed under a less stringent standard than those drafted by an attorney, and are provided a liberal construction. *Haines v. Kerner*, 404 U.S. 519 (1972). Nevertheless, a *pro se* litigant is still required to provide sufficient facts to support his claims, and “mere conclusory allegations on a critical issue are insufficient to raise a constitutional issue.” *United States v. Pineda*, 988 F.2d 22, 23 (5th Cir. 1993). Accordingly, “[a]bsent evidence in the record, a court cannot consider

a habeas petitioner's bald assertion on a critical issue in his pro se petition . . . to be of probative evidentiary value." *Ross v. Estelle*, 694 F.2d 1008, 1011 (5th Cir. 1983).

Defendant raises the following claims for ineffective assistance of trial counsel.

A. Plea Hearing

Defendant argues that counsel was ineffective at the plea hearing in failing to subject the prosecution's case to meaningful adversarial testing and failing to advise regarding the actual consequences. He complains that he was coerced into pleading guilty, promised a one-year sentence, and not advised of the relevant conduct provisions applicable at sentencing. Defendant's perfunctory allegations are unsupported and are refuted by the record in this case.

In the written plea agreement executed by Defendant at the plea hearing, Defendant agreed to the following factual basis for his plea:

In or about April 2003, the defendant established the Stowe Foundation as an entity with its mission to further medical research. The address given by the defendant for "The Foundation" was 6340 Lake Worth Boulevard, Fort Worth, Texas. This address was not a physical location, but a post office mailbox drop. In or about 2006, the defendant owned and operated Stowe Biotherapy Inc. (Stowe Biotherapy), a medical clinic located at 8431 La Mesa Boulevard in La Mesa, California. The defendant utilized Stowe Biotherapy and the Foundation to advertise, promote and distribute drugs and biological products that had not been reviewed and approved by the Food and Drug Administration (FDA) for the treatment of diseases in humans. Defendant knew that FDA approval is required before a drug or biological product can be introduced into interstate commerce for the treatment, prevention, mitigation, cure or prevention of disease in humans. The defendant also knew that FDA approval was required before he could introduce such products into interstate commerce for the treatment of disease in humans.

In or about January 2006, the defendant began to promote a medical treatment protocol that consisted of supplements, vitamins, vaccines and stem cell therapy. This protocol was called Applied Biologics. The defendant informed individuals suffering from amyotrophic lateral sclerosis (ALS) also known as Lou Gehrig's disease, multiple sclerosis (MS), Parkinson's and other neurological disorders that this treatment protocol would improve their medical condition. The defendant contacted a pathologist in Bryan/College Station, Texas to receive blood samples from patients for the purpose of growing bacteria that would later be used to create a product called patient specific transfer factors. The bacteria from patient's [sic] was then sent to a laboratory in South Carolina where the bacteria was ingested by chickens. The eggs produced by these chickens were later freeze dried and the powder from the eggs were placed in capsules and sold to patients. This product was not approved by the FDA for treatment of human diseases. The defendant also promoted and sold a product called Immune Factor G-40 to patients knowing [this] product was also not approved by the FDA for the treatment of human diseases.

In April 2007, codefendant Morales and the defendant entered into an agreement in which the defendant would purchase drug products called []immune modulation vaccine and cancer vaccine from the codefendant. The immune modulation vaccine was also referred to as SF 1090. During the period of May 9, 2007 and continuing through September 10, 2008, the defendant purchased from codefendant Morales drug products that he knew had not been approved by the FDA for the treatment of human diseases. The defendant promoted and sold this product in connection with an unapproved treatment regimen called "Applied Biologics" in which other unapproved drug products were used to treat individuals suffering from ALS, MS and Parkinson's. As part of the "Applied Biologics" treatment regimen, patients would receive unapproved drug products marketed by the defendant and codefendant Morales. The defendant charged patients between \$50,000.00 and \$125,000.00 for drug products that had not been approved by the FDA for the treatment of ALS, MS and Parkinson's.

In January 2010, the defendant was contacted by [an] individual named Michael Martin who was interested in the defendant's treatment regimen. Martin had been diagnosed with ALS. Currently there is no cure for ALS. The defendant informed Martin that he would benefit from his treatment protocol which had been reviewed by all levels of the FDA. This statement was not true. As a result, Martin paid the defendant \$47,000.00 for the defendant's treatment protocol that consisted [of] supplements, Immune

Factor G-40, and patient specific transfer factors. These products had not been approved by the FDA for the treatment of ALS or any other human disease.

(Docket Entry No. 74, p. 9–12.) This factual basis was read into the record at Defendant’s plea hearing, and Defendant testified on the record in open court that the facts were true. (Docket Entry No. 153, p. 17.) “A plea of guilty admits all the elements of a formal criminal charge and waives all non-jurisdictional defects in the proceedings leading to conviction.” *United States v. Owens*, 996 F.2d 59, 60 (5th Cir. 1993). Defendant here does not establish that counsel’s alleged deficient performance “directly affected the validity of waiver or the plea itself.” *White*, 307 F.3d at 343, and habeas relief is unwarranted.

Moreover, Defendant testified in open court at the plea hearing that he was “very satisfied” with trial counsel:

THE COURT: All right. Have you had enough time to talk to your attorney in this case?

THE DEFENDANT: Yes, Your Honor.

THE COURT: And are you satisfied with [trial counsel] as your attorney?

THE DEFENDANT: Very satisfied, Your Honor.

THE COURT: All right. Do you need to ask him any questions or get any further legal advice from him before we go on?

THE DEFENDANT: No, Your Honor.

(Docket Entry No. 153, pp. 5–6.)

Defendant further stated under oath on the record to this Court that his plea was voluntary and not coerced, that no one had made him any promises or guarantees as to his sentence, and that he understood the Court could use “relevant conduct” in determining his sentence at a later hearing:

THE COURT: All right. Mr. Stowe, this plea agreement has been reduced to writing. I assume you’ve gone over this with your attorney, correct?

THE DEFENDANT: Yes, Your Honor.

THE COURT: All right. Is that your understanding – what Mr. Louis just recited, is that your understanding of the terms of your plea agreement with the Government?

THE DEFENDANT: Yes, Your Honor.

THE COURT: All right. Now, there’s certain things that I need to advise you about with respect to your plea agreement. First of all, your agreement is with the United States Attorney’s Office in this case, and it does not restrict me or bind me in any way when I determine your sentence later on at the sentencing hearing. Do you understand that?

THE DEFENDANT: Yes, Your Honor.

THE COURT: All right. There’s an agreement in this case that certain counts of the indictment will be dismissed at sentencing. However, I will still know about the conduct that gave rise to those counts in the indictment, and I may have to consider that conduct as something called “relevant conduct” in determining ultimately what your sentence will be in this case. Do you understand that?

THE DEFENDANT: Yes, Your Honor.

THE COURT: All right. Now, I assume that [trial counsel] has gone over the Federal Sentencing Guidelines with you and how they may apply in your case; is that right?

THE DEFENDANT: Yes, Your Honor.

THE COURT: All right. Whatever [trial counsel] has told you with respect to the Sentencing Guidelines and how they might apply in your case – perhaps he's even given you an indication of what he thinks your sentence might ultimately be in this case – all of that is simply his best estimate of what's going to happen in this case based on his experience, but it is not a promise or a guarantee of any kind from [him] with respect to your sentence. You understand that?

THE DEFENDANT: Yes, Your Honor.

THE COURT: Nobody has made you any promise or guarantee of any kind with respect to your sentence; is that right?

THE DEFENDANT: That's right, Your Honor.

(Docket Entry No. 153, pp. 17–19.)

* * * *

THE COURT: All right. Now, when it comes to determining exactly what your sentence will be in this case, I'm not limited to information that the Government has today. Under certain circumstances, I can rely on information that is developed during the course of the pre-sentence investigation in imposing sentence, even if that information is not pleaded in the indictment or proven beyond a reasonable doubt; and that could potentially make your sentence longer as well. Do you understand that?

THE DEFENDANT: Yes, Your Honor.

Id. at 20.

THE COURT: At this time, Mr. Stowe, I need to ask you: What is your plea to the charges against you in Counts 1, 23, and 24?

THE DEFENDANT: Guilty, Your Honor.

THE COURT: All right. And do you state here in court under oath that each and every allegation in each of Counts 1, 23, and 24 is true and correct?

THE DEFENDANT: Yes, Your Honor.

THE COURT: And are you making this plea of guilty to Counts 1, 23, and 24 freely and voluntarily?

THE DEFENDANT: Yes, Your Honor.

THE COURT: Has anyone forced you, threatened you, coerced you, or done any violence to you or any other person to get you to plead guilty in this case?

THE DEFENDANT: No, Your Honor.

THE COURT: Are you pleading guilty because of any promise that's been made to you other than what is contained in your written plea agreement?

THE DEFENDANT: No, Your Honor.

THE COURT: Are you pleading guilty to protect someone else from criminal prosecution?

THE DEFENDANT: No, Your Honor.

THE COURT: Are you pleading guilty because you are guilty and for no other reason?

THE DEFENDANT: Yes, Your Honor.

THE COURT: All right. Have you read and do you understand the written plea agreement in this case?

THE DEFENDANT: Yes, Your Honor.

THE COURT: And are you prepared to sign it under oath at this time?

THE DEFENDANT: Yes, Your Honor.

Id., at 27–28.

A defendant may not refute his plea hearing testimony given under oath with statements made after conviction. *United States v. Fuller*, 769 F.2d 1095, 1099 (5th Cir. 1985). It is well established that “[s]olemn declarations in open court carry a strong presumption of verity,” creating a “formidable barrier in any subsequent collateral proceedings.” *Blackledge v. Allison*, 431 U.S. 63, 73–74 (1977). Defendant’s conclusory assertions do not meet this burden of proof. Nor does Defendant establish a factual basis supported in the record that counsel failed to advise him as to the consequences of pleading guilty. Defendant’s unsupported allegations provide no basis for habeas relief.

B. Pursuit of a Defense

Defendant next contends that counsel failed to pursue a defense and to investigate FDA reports in which the FDA did not follow procedural due process of law. Although the precise parameters of Defendant’s argument are not clearly stated, Defendant appears to argue that the FDA was required to give him a “notice of violation” and a hearing before he could be criminally prosecuted under the FDCA.

Defendant's argument is foreclosed by long standing Supreme Court precedent holding that notice and hearing are not prerequisites to criminal prosecution under the FDCA. *United States v. Dotterweich*, 320 U.S. 277, 278–79 (1943). As a result, Defendant establishes neither deficient performance nor actual prejudice under *Strickland*, and habeas relief is unwarranted.

C. *Mens Rea* Defense

Defendant claims that trial counsel failed to present a *mens rea* defense prior to sentencing. However, he fails to establish the existence of a valid *mens rea* defense. Defendant testified in open court and on the record that “each and every allegation in each of Counts 1, 23, and 24 [were] true and correct,” and that he was guilty as to those counts. (Docket Entry No. 153, p. 27.) Moreover, Defendant acknowledged in his written plea agreement that he used his companies to “advertise, promote and distribute drugs and biological products that had not been reviewed and approved by the Food and Drug Administration (FDA) for the treatment of diseases in humans,” “kn[owing] that FDA approval is required before a drug or biological product can be introduced into interstate commerce for the treatment,” and also knowing “that FDA review was required to determine the safety and effectiveness” of such drugs, and that “FDA approval was required before he could introduce such products into interstate commerce for the treatment of disease in humans.” (Docket Entry No. 74, pp. 9–10.)

Defendant fails to establish a valid *mens rea* defense that counsel should have raised. Defendant does not show that, but for counsel’s failure to raise such defense, he

would not have pleaded guilty and would have insisted on going to trial, and that going to trial would have given him a reasonable chance of obtaining a more favorable result. *Batamula*, 823 F.3d at 240. Defendant's conclusory assertions are unsupported in the record and provide no basis for granting habeas relief.

D. Sentencing

Defendant further argues that trial counsel should have challenged the calculations and relevant conduct presented by the Government at the sentencing hearing. He contends that counsel failed to challenge the Government's calculation of loss pursuant to *United States v. Santos*, 553 U.S. 507 (2008). Defendant argues that the objection had merit because "nearly all of the proceeds and 'self-funding' mechanisms of the Stowe Foundation were applied to the cost of operating a legitimate 501(c)(3) charity." Assuming this claim was not extinguished by Defendant's plea agreement waiver, it holds no merit.

Neither Defendant nor the record demonstrates any error in the calculations and relevant conduct presented by the Government at sentencing. How Defendant may have disposed of the money he obtained from victims of his criminal activities is of no moment to loss calculations under the relevant Sentencing Guidelines in his case. Under USSG § 2B1.1, the loss amount for sentencing purposes is defined, *inter alia*, as "the reasonably foreseeable pecuniary harm that resulted from the offense." In Defendant's case, and as reflected in the PSR, the pecuniary harm encompassed over \$400,000.00 that his victims paid to him, and Defendant's unsubstantiated conjecture of error establishes nothing to the contrary.

Moreover, Defendant's misplaced reliance on the *Santos* decision provides him no basis for habeas relief. In *Santos*, the Supreme Court addressed the definition of "proceeds" as it appears in the federal money-laundering statute, 18 U.S.C. § 1956(a)(1)(A)(i). *Santos*, 533 U.S. at 510–11. Defendant in the instant proceeding was not convicted of money laundering. Relevant to Defendant's conviction and sentencing was the "pecuniary harm" to the victims of his criminal conduct, and *Santos* provides Defendant no valid basis for relief.

Defendant fails to establish deficient performance and actual prejudice under *Strickland*, and his claim for ineffective assistance of counsel is without merit.

E. Actual Innocence

Defendant complains that trial counsel failed to assert Defendant's actual innocence. In this regard, Defendant appears to argue that he did not violate the criminal statutes to which he pleaded guilty because he neither manufactured nor altered the unapproved products, and worked with licensed physicians. Defendant's claim has no merit.

The elements of Defendant's criminal offenses were set forth by the Court on the record at the plea hearing, and Defendant pleaded guilty to the facts underlying those offenses. (Docket Entry No. 153, pp. 11–16, 24–27.) Defendant has not shown any relevant and factually supported grounds under which a reasonable jury would have found him not guilty of the charged offenses. Defendant's conclusory allegations are conjecture that establishes neither deficient performance nor actual prejudice under *Strickland*, and habeas relief is unwarranted. Moreover, Defendant's claim falls squarely within the

provisions of his plea agreement waiver and may not be pursued on section 2255 collateral review. Habeas relief is unwarranted.

Actual Innocence

Defendant asserts that he is “actually innocent” of the crimes to which he pleaded guilty because his conduct did not fall within the parameters of the statutory offenses. However, Defendant acknowledged in writing and testified in open court that the underlying facts establishing the criminal offenses set forth in the indictment were true, and that he waived his right to appeal or collaterally attack the resulting convictions. As a result, his claim of actual innocence was waived by his guilty plea and the written plea agreement.

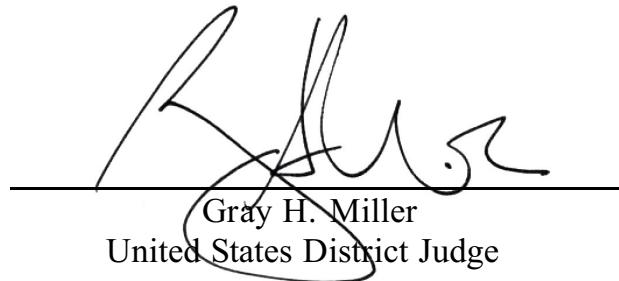
To the extent Defendant is raising a free-standing claim of actual innocence, no viable habeas claim is presented. It is well established that “actual innocence” is not a free-standing ground for habeas relief. *Foster v. Quarterman*, 466 F.3d 359, 367 (5th Cir. 2006) (“[A]ctual-innocence is not an independently cognizable federal habeas claim.”); *see also Matheson v. United States*, 440 F. App’x 420, 421 (5th Cir. 2011) (per curiam) (applying this rule in context of section 2255). Rather, it is a gateway to consideration of claims of constitutional error that otherwise would be barred from review. *See McGowen v. Thaler*, 675 F.3d 482, 499 (5th Cir. 2012). Consequently, Defendant is not entitled to habeas relief on his free-standing claim for actual innocence.

Conclusion

The Court ORDERS as follows:

- (1) The Government's motion to dismiss (Docket Entry No. 200) is GRANTED and Defendant's section 2255 motion and supplemental motion for relief (Docket Entries No. 189, 194) are DENIED.
- (2) Defendant's request for an evidentiary hearing is DENIED. The record in this case was adequate for a fair disposition of the habeas claims, and no hearing is necessary.
- (3) Defendant's motion to proceed *in forma pauperis* (Docket Entry No. 207) is DENIED for his failure to submit the required financial information and copy of his prison trust account statement.
- (4) Defendant's typewritten motion for extraordinary relief (Docket Entry No. 208) is unsigned and is STRICKEN FROM THE RECORD.
- (5) A certificate of appealability is DENIED.
- (6) Civil Actions No. H-16-1490 and No. H-16-1593 are ORDERED ADMINISTRATIVELY CLOSED.

Signed at Houston, Texas on November 7, 2017.



Gray H. Miller
United States District Judge